(21)

No. 03-1237

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In The
Supreme Court of the United States

MERCK KGaA,

Petitioner,

v.

INTEGRA LIFESCIENCES I, LTD.
and THE BURNHAM INSTITUTE,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF *AMICI CURIAE* CONSUMER PROJECT ON TECHNOLOGY, ELECTRONIC FRONTIER FOUNDATION AND PUBLIC KNOWLEDGE IN SUPPORT OF PETITIONER

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STATEMENT OF INTERESTS OF *AMICI CURIAE*

This brief *amici curiae* in support of Petitioner is submitted pursuant to Rule 37 of the Rules of this Court.[1]

Consumer Project on Technology (CP Tech) is a public interest non-profit organization founded by Ralph Nader in 1995. CP Tech represents the public who are the ultimate beneficiaries of the invention of new technologies. CP Tech is concerned that a narrow understanding of the experimental use exception will delay or impede scientific and technological developments that benefit the public.

Electronic Frontier Foundation (EFF) is a non-profit, membership-supported civil liberties organization working to protect consumer interests, innovation and free expression in the digital world. EFF and its 15,000 dues-paying members are concerned to assure that public benefits result from research and innovative efforts unencumbered by patent litigation and licensing threats.

Public Knowledge (PK) is a public-interest advocacy organization dedicated to fortifying and defending a vibrant information commons. PK is concerned that information protected by patents should remain free for use in scientific research and technological innovation.

CP Tech and PK filed an amicus brief in support of the Petition for Certiorari in *Duke University v. Madey*, No. 02-1007,

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[1] Letters from all parties consenting to the filing of this brief have been filed with the Clerk of this Court. No counsel for a party authored this brief in whole or in part, and no person or entity other than *amici curiae*, or their counsel, made a monetary contribution to the preparation or submission of this brief. American University, Washington College of Law student Cynthia Lan and Glushko-Samuelson Intellectual Property Law Clinic students Scott Brairton and Nayoung Kim assisted in drafting and preparing this brief under the supervision of Joshua Sarnoff.

urging this Court to review the narrow construction given to the experimental use exception in that case.

SUMMARY OF ARGUMENT

For almost 200 years, federal courts have recognized that Congress limited exclusive patent rights so as to protect scientific research and competitive evaluation to improve on patented inventions. The courts thus articulated a broad "experimental use exception" to patent infringement. In 1984, Congress enacted Section 271(e) of the Patent Act to overturn the decision of the U.S. Court of Appeals for the Federal Circuit in *Roche Products Inc. v. Bolar Pharmaceuticals Co.*, 733 F.2d 858 (Fed. Cir. 1984). That decision had applied an improperly narrow interpretation of the experimental use exception to scientific tests with a patented pharmaceutical compound for the purpose of obtaining generic product marketing approval from the Food and Drug Administration (FDA). In response to *Roche*, Congress restored the experimental use exception to (and beyond) its prior scope for uses of patented inventions "reasonably relating" to the development or submission of information to obtain marketing approval. By enacting Section 271(e), Congress reversed rather than ratified the *Roche* court's improperly narrow interpretation of the experimental use exception to Section 271(a). Section 271(e) thus applies to actions with patented inventions that are not wholly unrelated to developing information for the regulatory approval process and that, under the rejected *Roche* interpretation, would not have qualified for the experimental use exception. Accordingly, Section 271(e) and the experimental use exception provide overlapping protection.

The language of Section 271(e) confirms Congress' understanding of the broad historic scope of the experimental use exception to Section 271(a). Congress never intended for the exclusive patent rights of "making" and

"using" to apply to scientific research with or competitive evaluation of patented inventions. Such activities do not deprive patentees of any commercial rewards to which they are entitled. Commercial competitors thus have been free to make and use patented inventions to develop improvements, but not to sell or use patented inventions commercially during the patents' terms. Similarly, Section 271(e)(1) broadly excludes from infringement all making and using of patented inventions by scientists and commercial competitors solely to develop information to seek approval of regulated products. Section 271(e)(2) prohibits the submission of data for approval (but not the underlying experiments) only for the purpose of obtaining approval to compete commercially by selling patented products during the patent term.

The legitimate *in vitro* and animal experiments at issue in this case were performed to develop information for FDA approval. Thus, this Court should confirm that both the experimental use exception and Section 271(e) apply here. Long-standing legislative policy supports protecting such scientific research and competitive evaluation. This Court's guidance is urgently needed in light of the Federal Circuit's recent decisions in this case and in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002). The Federal Circuit's narrow interpretations of the experimental use exception substantially chill scientific research and competitive development of new technologies in the United States. The ability to experiment free from the threat of patent infringement or from the tax of patent licenses is critical to scientists and to competitors seeking to develop non-infringing or blocking improvements. A broad experimental use exception is therefore essential to furthering scientific knowledge and technological development to benefit humanity.

ARGUMENT

I. Section 271(e) And The Experimental Use Exception Provide Overlapping Protection.

A. The Federal Circuit In *Roche* Improperly Limited The Experimental Use Exception.

In *Roche*, the Federal Circuit reversed the District Court's holding that the experimental use exception applied. The District Court had found that use by a generic manufacturer of an imported, patented pharmaceutical compound for "FDA required testing and experimentation before the patent expires" did not constitute infringement, given that the generic drug manufacturer did not intend to obtain regulatory approval to market its product during the patent term. *Roche Prods. Inc. v. Bolar Pharms. Co.*, 572 F. Supp. 255, 256-57 (E.D.N.Y. 1983). Relying on numerous precedents, and notwithstanding the defendants' concession that the experimental use exception did not apply, the District Court had held there was no infringement because there was no "act of competition or profit during the term of the patent in either domestic or foreign markets." *Id.* at 257 (*citing, inter alia, Kaz Mfg. Co. v. Chesebrough-Ponds, Inc.*, 211 F. Supp. 815 (S.D.N.Y. 1962), *aff'd*, 317 F.2d 679 (2d Cir. 1963); *Chesterfield v. United States*, 159 F. Supp. 371 (Ct. Cl. 1958); *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223 (S.D.N.Y. 1944), *aff'd*, 156 F.2d 29 (2d Cir. 1946); and *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305, 333 (N.D.W.V. 1937); and *rejecting Pfizer, Inc. v. International Rectifier Corp.*, No. 73-58, 1982 U.S. Dist. LEXIS 17411 (C.D. Cal. July 20, 1982)).

The Federal Circuit reversed the District Court and imposed a much more restrictive interpretation of the experimental use exception. Quoting inapplicable dicta

from *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976),[2] the Federal Circuit held that the exception did not apply to the legitimate experiments at issue: "'[t]ests, demonstrations, and experiments . . . in keeping with the legitimate business of the . . . [alleged infringer]' are infringements for which '[e]xperimental use is not a defense.'" *Roche*, 733 F.2d at 863 (*quoting Pitcairn*, 547 F.2d at 1125-26). Although it recognized that the cases relied on by the District Court were binding, the Federal Circuit found those cases to be "unpersuasive." *Id.*

The Federal Circuit thus improperly characterized the experimental use exception as "truly narrow" and expanded commercial infringements to include all "unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimentor's business. . . ." *Id.* Relying on inaccurate dicta from *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279),[3] the Federal Circuit limited the exception to experiments performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry,"

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[2] *Pitcairn* did not address scientific research or competitive evaluation to develop improvements. *See id.* at 1125 ("there is no evidence . . . that any of the helicopters to which defendant's 'experimental use' contentions pertain were built solely for experimental purposes. . . . Numerous research and development contracts were entered . . . for the design, development and manufacture of experimental helicopters and none of those specific helicopters are the subject of this litigation."). Rather, *Pitcairn* addressed quasi-commercial product testing to assure that helicopters manufactured for the U.S. Government conformed to their specifications and were suitable for intended uses. *See id.* at 1125-26.

[3] *Falke* addressed unspecified, purported experiments by competitors who were former employees "perfectly familiar with [the] patents and processes" and who did not need to experiment with the patentee's invention "in order to perfect their own." *Id.* at 1049. *Falke* recognized that the exception was "well settled," but wrongly stated that it was available "for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement." *Id.*

or alternatively as a "dilettante affair such as Justice Story envisioned." *Id.* As discussed in Part II, Justice Story envisioned no such thing.

B. Congress Enacted Section 271(e) To Reverse *Roche*'s Narrow Interpretation.

The *Roche* decision provoked swift legislative disapproval. *Roche* was decided by the Federal Circuit on April 23, 1984. Within five months, Congress responded with what became Section 271(e) of Title 35. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (1984). That provision reversed the Federal Circuit's narrow interpretation of the experimental use exception as it applied to activities of commercial entities seeking to obtain governmental approval to market their drugs. As adopted, Section 271(e)(1) provided that "it shall not be an act of infringement to make, use or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." *Cf.* 35 U.S.C. § 271(a) (whoever "makes, uses, offers to sell, or sells any patented invention, within the United States, or imports . . . infringes").[4]

Section 271(e) was included as a late addition to legislation already under consideration to expedite generic product approvals and to extend pioneering patent terms, and legislative debate on that section focused on whether

[4] Congress later amended Section 271(e) to extend these protections to uses for approval of veterinary biological products and to except from infringement offers for sale and imports (when those rights were added to Section 271(a)). *See* Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, § 201, 102 Stat. 3971, 3988 (1988); Uruguay Round Agreements Act, Pub. L. No. 103-465, § 533, 108 Stat. 4809, 4988 (1994).

it constituted a taking. *See Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 404 (Fed. Cir. 1989); *Allergan, Inc. v. Alcon Labs., Inc.*, 200 F. Supp. 2d 1219, 1226 (C.D. Cal. 2002).[5] Section 271(e) thus was grafted onto the compromise to accomplish a different purpose, although it related to the previously negotiated provisions.[6]

As the 98th Congress intended and as numerous courts have since recognized, "Congress enacted § 271(e) in 1984 in order to reverse the experimental use exception holding of the United States Court of Appeals for the Federal Circuit in *Roche*." *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1276 (N.D. Cal. 1991). *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 n.3 (1990) ("Undoubtedly the decision in *Roche* prompted the *proposal* of § 202"); *Eli Lilly & Co.*, 872 F.2d at 405 (the legislation "overruled *Roche* by adding section 271(e)"); H.R. REPT. NO. 98-857, pt. 2, at 26-27 (1984) ("'*Roche* was wrongly decided . . . Congress did not intend the word "uses" in § 271(a) to extend so broadly.'") (citation omitted); *id.* at 27 ("The provisions of section 202 of the bill have the net effect of reversing the holding of the court in

[5] As introduced, H.R. 3605 had sought only to create an abbreviated process for generic drug approval and did not contain any patent provisions. *See* H.R. 3605, 98th Cong. § 2 (1983). Between 1980 and when *Roche* was decided, Congress had considered bills to extend (or "restore") patent terms for products subject to approval under various Federal health and environmental laws. *See, e.g.*, S. 2892, 96th Cong. § 3 (1980); H.R. 1937, 97th Cong. § 1 (1981). These bills did not provide any exception from infringement, as it would not have been thought necessary to do so before *Roche*. *See also* S. 1306, 98th Cong. § 2 (1983); H.R. 3502, 98th Cong. § 2 (1983). Representative Henry Waxman brokered a compromise in 1983 to accomplish both purposes for drugs. *See, e.g., Allergan, Inc.*, 200 F. Supp. 2d at 1225-26.

[6] Senator Orrin Hatch introduced bills containing similar language to that added to H.R. 3605. *See* S. 2748, 98th Cong. § 202 (1984); S. 2926, 98th Cong. § 202 (1984). Senator Hatch then negotiated further changes that did not affect Section 271(e) in order to overcome opposition from pioneering manufacturers. *See Allergan, Inc.*, 200 F. Supp. 2d at 1227.

Roche"); H.R. REPT. NO. 98-857, pt. 1, at 74 (1984) (minority views of Rep. Bliley) ("H.R. 3605 . . . would overrule *Bolar*"); 130 CONG. REC. H8712-13 (1984) (remarks of Rep. Kastenmeier) ("The Bolar case, then, will be overruled by this bill."); 130 CONG. REC. H24456 (1984) (remarks of Rep. Moorhead) (the bill "would retroactively overrule the recent Federal Court of Appeals decision in Roche against Bolar"). Congress clearly disapproved of the implications of the Federal Circuit's narrow interpretation of the experimental use exception, and not just of its application to the facts in *Roche*. *See Eli Lilly & Co.*, 496 U.S. at 669-79 (holding that the exclusion applies to the same subject matter as the term extension provisions, including products that were not at issue in *Roche*).

By enacting Section 271(e), Congress reinstated a broader *interpretation* of the experimental use exception under Section 271(a). As articulated by Judge Nies in *Eli Lilly & Co.*:

> The clear intent of Congress was to create an FDA experimental use exception for use which *Roche* had held would constitute infringement under section 271(a). . . . No statutory language in section 271(a) is repealed by implication. Rather, the *Roche interpretation* of the language of section 271(a) is necessarily repealed (that is, by implication) by the addition of section 271(e)(1). . . . Congress intended the enactment of Section 271(e)(1) to set aside the *Roche* interpretation of Section 271(a) in all of its ramifications.

872 F.2d at 406 (*citing United States v. Fausto*, 484 U.S. 439, 453 (1988), for the relevant statutory construction principle).

Congress thus reversed rather than ratified the Federal Circuit's narrow interpretation of the experimental use exception in *Roche*. Congress did not approve of Federal Circuit's continued application of that narrow interpretation outside the context of Section 271(e), much

less authorize the further constrictions of the experimental use exception discussed in Part III. *Cf. Alexander v. Sandoval*, 532 U.S. 275, 292 (2001) (when Congress makes "only isolated amendments . . . '[i]t is "impossible to assert with any degree of assurance that congressional failure to act represents" affirmative congressional approval of the Court's statutory interpretation.'") (*quoting Patterson v. McLean Credit Union*, 491 U.S. 164, 175 n.1 (1989)) (citation omitted). Nor has Congress since impliedly ratified the Federal Circuit's interpretations. *See Jama v. Immigration and Customs Enforcement*, 125 S. Ct. 694, 704 (2005) (legislative ratification requires reenactment without change and a judicial consensus "so broad and unquestioned that we must presume that Congress knew of and endorsed it"). *Cf. Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 873-75 (Fed. Cir. 2003) (Newman, J., dissenting) (evidencing the lack of consensus). Rather, Congress has continued to disapprove of *Roche* and its progeny.[7]

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[7] *See, e.g.*, H.R. 3967, 107th Cong. § 2 (2002); H.R. 5598, 101st Cong. § 402 (1990); H.R. 4970, 100th Cong. § 2 (1988). *See also* H.R. REPT. NO. 101-960, pt. 1, at 41-43 (1990) (discussing the "research exception," noting that "'the framers of the Constitution clearly could not have envisioned shutting the door to further research for the long period of the patent grant,'" and urging codification to avoid confusion regarding permissible scientific research) (citation omitted); Nat'l Acad. Sci., *A Patent System for the 21st Century* 93 (Nat'l Research Council 2004) (recommending codification); Am. Int'l Prop. L. Assoc., *AIPLA Response to the National Academies Report entitled "A Patent System for the 21st Century,"* at 23-27 (2004) (same), available at http://www.aipla.org/Content/ContentGroups/Issues_and_Advocacy/Comments2/Patent_and_Trademark_Office/2004/NAS092304.pdf. Nor can approval be inferred because these bills have not been enacted. *See, e.g., Alexander*, 532 U.S. at 292 (*citing Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 187 (1994)).

C. Both Section 271(e) And The Experimental Use Exception Apply To Acts That Would Infringe Under The Rejected *Roche* Interpretation.

By enacting Section 271(e), Congress intended to reverse the interpretation of *Roche* that had treated as infringement scientific research with patented inventions performed at *any* stage of the drug research and development process, based solely on a commercial intent to market drugs in the future. This Court should therefore interpret Section 271(e) broadly, as its language requires. Section 271(e) applies to specified acts with patented inventions "solely for uses reasonably related to the development and submission" of information for regulatory approval. The language of the exclusion is categorical, applying even to patented inventions that are not themselves the subject of the regulatory approval when used solely for such purposes.

This Court should not limit its interpretation of "reasonably related" to experiments intended to generate information actually included in regulatory approval submissions. Congress could not have intended to leave a gap between basic research qualifying for the experimental use exception under *Roche* and Section 271(e), authorizing injunctions as soon as a promising product had been identified or once a commercial intent had been acquired. To do so would allow patentees to stop the product approval process dead in its tracks. *See Integra LifeSciences I, Ltd.*, 331 F.3d at 877 (Newman, J., dissenting) ("the law does not favor such an illogical outcome").

Rather, this Court should interpret "reasonably related" to apply to all activities performed at any stage of a research and development process leading to regulatory approval that, under the rejected *Roche* interpretation, would not have qualified for the experimental use exception. Under this interpretation, Section 271(e)

applies unless the experiments: (1) have absolutely nothing to do with seeking regulatory approval (and thus any asserted relation would be unreasonable); or (2) would not have infringed under the *Roche* interpretation (and thus Section 271(e) would not have been needed). This interpretation is supported by the language of Section 271(e), which links "reasonably related" to the "development" of information. More constricted alternative interpretations either would require unwarranted dissection of the term "development" or would render it surplusage. *See, e.g., Leocal v. Ashcroft*, 125 S. Ct. 377, 382 (2004); *TRW, Inc. v. Andrews*, 534 U.S. 19, 31 (2001).[8]

This means that Section 271(e) and the experimental use exception to Section 271(a) overlap. Both Section 271(e) and the experimental use exception (properly understood) apply to making and using of patented inventions that would have infringed under the rejected *Roche* interpretation and that occur during a research and development process leading to regulatory approval. Only the experimental use exception applies to making and using of patented inventions that would not have infringed under the *Roche* interpretation (as discussed in Part II) or that is wholly unrelated to seeking regulatory approval. And only Section 271(e) applies to offering for sale, selling, or importing the patented invention for use in seeking such approval.

[8] Nor should any constricted interpretation of Section 271(e) be inferred from the terms "solely for uses." *But see Integra LifeSciences I, Ltd.*, 331 F.3d at 866. As discussed below, legitimate science and competitive improvement have always been distinguished from purported experiments that were actually commercial activities using patented inventions. The terms "solely for uses" reflect this history.

II. The Experimental Use Exception Broadly Protects Scientific Research and Competitive Evaluation.

A. Congress Never Prohibited Scientific Research With Or Competitive Evaluation Of Patented Inventions.

The experimental use exception to patent infringement was first articulated by Justice Story in *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600). He indicated that a proper construction of the statutory property rights enacted by Congress did not extend to the broadest literal interpretation of the exclusive "making, constructing, using, and vending to others to be used, the said invention or discovery." Patent Act of 1793, ch. 11, § 1, 1 Stat. 317, 317 (1793) (currently codified as amended at 35 U.S.C. § 271(a)).[9] Justice Story explained that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." *Whittemore*, 29 F. Cas. at 1121. Justice Story parsed the limits to the exclusive

[9] It is important not to conflate the experimental use exception to infringement with the equitable doctrine *de minimis non curat lex* in cases of infringement. *See, e.g., Douglas v. United States*, 181 U.S.P.Q. 170, 176 (Ct. Cl. Trial Div. 1974) (*citing Radio Corp. of Am. v. Andrea*, 15 F. Supp. 685, 687 (E.D.N.Y. 1936), *modified*, 90 F.2d 612 (2d Cir. 1937)), *aff'd on other grounds*, 510 F.2d 364 (Ct. Cl. 1975). *Cf. Embrex, Inc. v. Serv. Eng. Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (treating these issues as distinct). Experimental use is not infringing conduct, even though the patentee may thereby be deprived of potential sales or other value. *Cf.* 17 U.S.C. § 107 (listing specific conduct and copyright fair use factors); 17 U.S.C. §§ 108-12 (listing specific conduct excepted from copyright infringement). Defendants need not plead and do not bear the burden of proving experimental use. *Cf.* Donald S. Chisum, 6 *Chisum on Patents* § 19.01 (2004) (non-infringement "is, precisely speaking, not a defense").

property rights in the alternative, excluding from the meaning of the statutory language both philosophical experiments with and evaluations of described inventions. As commonly understood at the time, philosophical experiments meant scientific research in general and research on physical principles in particular.[10]

As Justice Story elaborated in *Sawin v. Guild*, 29 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391):

> the making of a patented machine to be an offence within the purview of it, must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification. . . . In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.

Id. at 555 (citing *Whittemore*). Those "lawful rewards" included selling the patented invention in competition with the patentee, but did not include making or use by a scientist engaged in research or by a competitor to test the

[10] *See, e.g.*, II *The Compact Edition of the Oxford English Dictionary* 2154 (Oxford U. Press 1971) (defining "[p]hilosophical" as "[p]ertaining to, or used in the study of, natural philosophy, or some branch of physical science"); William Shakespeare, *Hamlet*, in The Riverside Shakespeare at 1151 n.167 (Houghton Mifflin 1974) (defining "philosophy" as "natural philosophy, science" in regard to Hamlet's famous line to Horatio at I.v.166-67); *A Visit to Henkel's Warerooms*, XLI Godey's Lady's Book 123 (Philadelphia, PA, Aug. 1850) (discussing "philosophical experiments . . . of great value in the construction of furniture"); *Education of Farmers*, The Colored American (New York, NY, July 27, 1839) (treating nature as "a laboratory where chemical and philosophical experiments are going on upon a larger scale"); *Pennsylvania Gazette* (Jan. 13, 1790) (discussing receipt of "a Philosophical Apparatus" for exhibiting "a whole course of experiments in natural philosophy and astronomy"); *Pennsylvania Gazette* (Apr. 6, 1785) (advertising to "make and repair Thermometers and Barometers, likewise all kinds of Glasses for philosophical experiments").

validity and scope of the patent or to design non-infringing substitutes or blocking improvements.[11] As Justice Curtis later explained, the premise of *Whittemore* and *Sawin* was that scientific research and competitive evaluation do not cause injury to the exclusive patent right and are not performed "with an intent to deprive the patentees of some lawful profit." *Byam v. Bullard*, 4 F. Cas. 934, 935 (C.C.D. Mass. 1852) (No. 2,262) (also holding that the exclusive right of "vending to others to be used" under the 1836 Patent Act did not include sales made to the patentee). *See Poppenhusen v. New York Gutta Percha Comb Co.*, 19 F. Cas. 1059, 1063 (C.C.S.D.N.Y. 1858) (No. 11,283) ("when there has been no profit and no sale, it will not make a party liable, because the patentee would not be injured by it").

The experimental use "exception" thus demarcates conduct that has always been outside the scope of actions prohibited by the grant of exclusive rights for limited times. *See* U.S. Const., Art. I, § 8, cl. 8. As Congress recognized when enacting Section 271(e), the ability to dominate research and development of competitive alternatives during the patent term would, in effect, result in improper extension beyond the patent term of the right to exclude. *See* H.R. REPT. NO. 98-857, pt. 1, at 46 (1984). Congress thus reiterated that "[t]here should be no other direct or indirect method of extending patent term" than the express provisions for term extension. *Id.* This Court

[11] *See* Patent Act of 1793, ch. 11, § 2, 1 Stat. 317, 318 (1793) (describing the legal effect of blocking improvement patents). *Cf. Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163, 171 n.5 (1931) (discussing economic effects of blocking improvement patents). Blocking is common in regard to patentable improvements of broad original (pioneering) patented inventions and to patentable new uses of patented inventions. *See, e.g., Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809-10 (Fed. Cir. 2002); *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1379 n.2 (Fed. Cir. 2000).

has previously effectuated this legislative intent in regard to patent licenses when judicial enforcement of misused patent rights would effectively extend patent terms. *See Brulotte v. Thys Co.*, 379 U.S. 29, 30-31, 32-33 (1965) (holding that royalty payments that project beyond the patent term are per se illegal). *Cf. Special Equipment Co. v. Coe*, 324 U.S. 370, 377-80 (1945) (narrowly rejecting a challenge to issuance of a broader patent, for intentional failure to "work" the invention, given that the patent prevented commercial use of competitive substitutes to a narrower patented invention and thus eliminated competitive incentives to develop substitutes during the narrow patent's term).

B. The Experimental Use Exception Applies To All Making And Using (But Not Selling) For Research And Evaluation.

Although sparse, the case law applying the experimental use exception makes clear that research by scientists and evaluations by competitors to develop improvements did not qualify as acts of infringement. For example, in *Chesterfield v. United States*, 159 F. Supp. 371 (Ct. Cl. 1958), the court held that governmental use of a purchased new alloy (that met the patented range of claimed alloy compositions) solely "for testing and for experimental purposes" did not infringe, and stated categorically that "[e]xperimental use does not infringe." *Id.* at 375-76. *See* Steven P. Caltrider & Paula Davis, *The Experimental Use Defense: Post-*Madey v. Duke *and* Integra LifeSciences I, Ltd. v. Merck KGaA, 86 J. Pat. & Trademark Off. Soc'y 1011, 1015 (2004) (3,679 pounds of a new alloy within the scope of the claims were produced by a contractor at the government's request and ultimately tested for its potential as "turbo-supercharger buckets" for jet engines). Similarly, in *Ruth v. Stearns-Roger Manufacturing Co.*, 13 F. Supp. 697 (D. Col. 1935), *rev'd on other grounds*,

87 F.2d 35 (10th Cir. 1936), the District Court reduced the damage award by excluding commercial sales of replacement parts to the Colorado School of Mines, which parts were used only experimentally in patented machines "in the laboratory . . . [that were] cut up and changed." *Id.* at 703. The defendant had no contributory liability for these sales, because the experimental uses could not constitute an infringement. "The making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement." *Id.* at 713. *See also Ordinance Eng. Corp. v. United States*, 84 Ct. Cl. 1, 2 (1936) (excluding from an infringement accounting experimental shells "built for experimental purposes").

Evaluation of patented inventions by commercial competitors to develop non-infringing or blocking improvements also did not constitute infringement, although such making and using would not confer a right to subsequently sell or commercially use the same or other patented inventions in the normal course of business (what Justice Story had called use for profit). *See Dugan*, 55 F. Supp. at 224, 229 (finding no infringement from a competitor's experimental making of a direction-finding system); *Akro Agate Co.*, 18 F. Supp. at 333 (finding no infringement from a competitor's experimental use before commercial production of a non-infringing substitute).[12]

[12] *See also Kaz Mfg. Co.*, 317 F.2d at 680-81 (holding that use of the patented invention in comparative advertising did not infringe); *Levin v. Ripple Twist Mills, Inc.*, 416 F. Supp. 876, 881 n.9 (E.D. Pa. 1976) (noting that "[t]he manufacture and experimental use of a machine which is covered by a patent is not an infringement unless and until the machine is put to a commercially valuable use"); *Ling-Temco-Vought, Inc. v. Kollsman Instr. Corp.*, No. 61-C-590, 1966 U.S. Dist. LEXIS 7967, at *70 (E.D.N.Y. Feb. 10, 1966) (holding that a public demonstration of a patented invention to solicit government contracts was not an infringement). *Cf. Albright v. Celluloid Harness-Trimming Co.*, 1 F. Cas. 320, 323 (C.C.D.N.J. 1877) (No. 147) (finding "a technical infringement"

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Where the asserted experimental use was not legitimate, however, the experimental use exception did not apply. Thus, the somewhat larger number of cases rejecting claims of experimental use all involved either commercial sales of patented inventions (whether or not they were blocking improvements) during the patent term or commercial uses that were not fairly characterized as research or evaluation to assess patent validity or to design improvements.[13] Similarly, competing commercial sales of

but refusing relief because of the lack of "damage or profits"). *See generally* Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. Pat. Off. Soc'y 617, 625 (1985) (distinguishing use for profit from cases in which "the experimenter neither made money nor tried to make money *while* infringing the patented invention") (emphasis added); *id.* at 625-38 (discussing cases).

[13] *See, e.g., Pitcairn*, 547 F.2d at 1125-26 (finding infringement from government testing of specially procured helicopters to assure they conformed to product specifications, as "intended uses . . . and are in keeping with the legitimate business of the using agency"); *Cataphote Corp. v. De Soto Chem. Coatings, Inc.*, 356 F.2d 24, 27 (9th Cir. 1966) (finding infringement from testing to "ascertain[] . . . the product's marketability" and distinguishing "an inventor's[] experiment"); *Radio Corp. of Am.*, 90 F.2d at 614-15 (finding infringement from product marketability testing of vacuum tubes in receivers, prior to shipment for overseas sales); *National Meter Co. v. Thomson Meter Co.*, 106 F. 531, 541-42 (C.C.S.D.N.Y. 1900) (finding threatened infringement from the manufacture and stockpiling of six water meters and additional castings and parts, warranting an injunction and an accounting); *Clerk v. Tannage Patent Co.*, 84 F. 643, 644 (C.C.A. 3d 1898) (finding infringement from willful testing of patented processes to determine "desirability or utility" following a patentee's offer to grant a license); *Bonsack Machine Co. v. Underwood*, 73 F. 206, 211-12 (E.D.N.C. 1896) (finding infringement because the competitor used the patented machine to assist sale of his own patent and to establish a company to produce goods for sale under the patent); *Douglas*, 181 U.S.P.Q. at 177 (finding infringement from continuous use by various military services of jet airplanes and replacement engines for their intended purposes, as not "*merely* experimentation"); *Radio Corp. of Am.*, 15 F. Supp. at 687 (finding infringement and distinguishing product testing from "a scientific research or an engineering inquiry"); *Cimiotti Unhairing Co. v. Derboklow*, 87 F. 997, 999 (E.D.N.Y. 1898) (finding infringement from stripping of hair from customers' fur pelts using the patented invention

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patented inventions for experimental making and using infringed the exclusive right of vending to others (now selling or offering for sale). *See Ruth*, 13 F. Supp. at 700 Table B, 701 Table C, and 708 Table M (including sales of completed machines to the Colorado School of Mines in the damage accounting). *Cf. Giese v. Pierce Chem. Co.*, 29 F. Supp. 2d 33, 35-37 (D. Mass. 1998) (suggesting that there could be no contributory liability from selling unpatented *products* to academic researchers for experimental use in patented *methods*, because the research itself was excepted from infringement, but that such sales could have directly infringed a hypothetical *product* patent even if the research was excepted).

In summary, until *Roche*, none of the experimental use cases found infringement from research or evaluation that resulted in selling or commercial use of *unpatented* products during the patent term or of patented products *after* the patent expired.[14] *See* Steven J. Grossman, *Experimental Use or Fair Use as a Defense to Patent Infringement*, 30 IDEA 243, 257 (1990) (responding to the argument that competitive improvement might "replace the patented invention in the market place, the answer given is that's exactly what the patent system is supposed to do") (*citing* Hantman, 67 J. Pat. Off. Soc'y at 643). Nor do these cases suggest that *legitimate* experiments could themselves infringe because followed by infringing sales of patented

in the ordinary course of business, which did not constitute "legitimate use for experimental purposes only"). *See generally* Hantman, 67 J. Pat. Off. Soc'y at 628-30, 635-37 (describing additional cases involving commercial uses).

[14] This is true even of *Pfizer, Inc.*, which addressed a contempt hearing on post-injunction conduct. The defendant continued to produce and to send overseas samples of patented drug products labeled as "for experimental use" in order to procure foreign sales, and submitted bioequivalency studies to FDA only to support its foreign sales. *Pfizer, Inc.*, at *1-*10.

products during the patent term. The uses either were experimental or were uses for profit. Thus, commonly cited dicta from Professor Robinson's historic treatise should be understood to describe only patented inventions produced by or used in purported experiments that were actually making and use for profit. *See* William Robinson, *The Law of Patents for Useful Inventions* § 898 (1890) ("if the products of the experiment are sold, or used for the convenience of the experimentor, or if the experiments are conducted with a view to the adaptation of the invention to the experimentor's business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent").[15]

In 1952, Congress codified the direct infringement right in Section 271(a), preserving the historic parameters of direct infringement law (except in regard to contributory liability) and thus of the experimental use exception.[16] Federal courts have remained free since that time to apply the experimental use exception to the same extent as before. As the principal author of the 1952 Patent Act later remarked when dismissing concerns that issuing broad chemical claims might threaten scientific research,

[15] Professor Robinson may have improperly construed dicta from *New York Gutta Percha Comb Co.*, that use of a patented process "done as a matter of business, where the product of that experiment has been thrown into the market, to compete with the products of the plaintiff, although he may call it an experiment, yet, if it is a matter of business, and thrown into the market for the purpose of being sold, and is sold with his other products, why, that will be such a use as will make the party liable." 19 F. Cas. at 1063. The court in *New York Gutta Percha Comb Co.*, however, was distinguishing legitimate experiments with a patented process from intended production and sale of the product of using the process during the term of the patent.

[16] *See, e.g., Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 26-27 (1997); H.R. REPT. NO. 82-1923, at 5 (1952); Pasquale J. Federico, *Commentary on the New Patent Act, reprinted in* 75 J. Pat. Off. Soc'y 161, 170 (1993).

"experimental use is not an infringement." *In re Kirk*, 376 F.2d 936, 965 (C.C.P.A. 1967) (Rich, J., dissenting).

C. The Language Of Section 271(e) Confirms The Scope Of The Experimental Use Exception.

The language of Section 271(e) reflects this history, distinguishing non-infringing scientific research and competitive evaluation from infringing use for profit during patent term. Section 271(e)(1) is categorical in applying to all making and using of patented inventions during the patent term for scientific research and competitive evaluation reasonably related to developing products for approval. Section 271(e)(1), however, went even further than the experimental use exception, by extending protection to sales (and later to offers to sell and to imports) for legitimate research and evaluation. Congress thus chose to prevent patentees from using their exclusive rights to delay scientific and technological progress during the patent term. Nevertheless, Congress continued to treat selling as an infringement when the patented inventions were not employed "solely for uses reasonably relating" to seeking regulatory approval, just as an infringing use for profit resulted if the experiments were not performed solely for research or for evaluation to develop improvements.

Section 271(e) also makes clear that legitimate scientific research or competitive evaluation is not a use for profit that deprives patentees of any lawful reward. *See* H.R. REPT. NO. 98-857, pt. 1, at 46 (1984) ("It is the Committee's view that experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of the patent"); H.R. REPT. NO. 98-857, pt. 2, at 8 (1984) (noting that the use authorized during the patent term "retains [to the patent holder only] the right to exclude others from the major commercial marketplace during the life of the patent"). Section 271(e)(2) thus

prohibits only the submission of data when intended for "approval . . . to engage in the commercial manufacture, use, or sale . . . before expiration of such patent." Conversely, Sections 271(e)(3) and 271(e)(4)(B) prohibit injunctions that would prevent experiments to develop such data, and Section 271(e)(4)(C) limits damages to actual commercial sales (excluding prior experimental uses leading to those sales). In Section 271(e)(4)(A), Congress even allowed the continued use of data submitted in violation of Section 271(e)(2), so long as approval for commercial sales does not result before the expiration of patent term. In summary, only sales or commercial uses of the patented invention during the patent term can infringe, and legitimate research and evaluation are not acts of infringement even when followed by infringing sales or commercial uses.

III. The Court Should Confirm That Congress Intended A Broad Experimental Use Exception To Promote The Progress Of Science and Technology.

A. The Court Should Find That Both Section 271(e) And The Experimental Use Exception Apply Here.

In *Brenner v. Manson*, 383 U.S. 519 (1966), this Court expressed concern that minimal invention or disclosure and broad patent claims could impede scientific research and technological development. *See id.* at 534 (focusing on the meaning of "useful" in 35 U.S.C. § 101 and noting that process patents in chemical fields "may confer power to block off whole areas of scientific development"); *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 257 (1928) (overly broad claims "foreclose efforts to discover" improvements and "discourage rather than promote invention"). Since that time, this concern has grown. Extremely broad generic claims now are routinely sought by inventors and issued by the Patent Office for discoveries

resulting from minimal creativity and intended for use principally in scientific research. *See, e.g., Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253-58 (Fed. Cir. 2004) (discussing complex standards for determining enablement of generic monoclonal antibody claims); *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 963-68 (Fed. Cir. 2002) (authorizing claims for genetic sequences identifiable only by performing experiments on a deposited cell, and remanding for evaluation of generic claims); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) (establishing written description requirements for generic claims to genetic sequences). *Cf. In re Fisher*, App. No. 2002-2046 (B.P.A.I. 2004), *appeal pending*, No. 04-1465 (Fed. Cir.) (rejecting claims for a broad genus of nucleic acid sequences containing a wide variety of expressed sequence tags useful primarily for research). *See generally* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698 (1998). The proliferation of patents on biotechnology inventions potentially threatens the ability of scientists to perform research having the greatest importance to society. *See* Organization for Economic Co-Operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* at 12-18 (2002) (discussing numerous concerns with the issuance, licensing, and effects on early disclosure and on collaboration of such patents).

These concerns apply with full force to the broad patent claims for a generic class of RGD peptides at issue here, which are asserted to apply to scientific research performed to develop a cure for cancer using the particular species of cyclic RGD peptides identified and selected by

Petitioner.[17] The disputed research includes *in vitro* and animal experiments performed by respected scientists prior to submitting an application to FDA for Investigational New Drug (IND) approval so as to permit human clinical tests, with the hope of later seeking FDA approval for commercial sales. *See* Brief for Plaintiffs-Cross Appellants Integra LifeSciences I, Ltd. and the Burnham Institute at 5-7, 21-22, *Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003) (No. 02-1052, -1065) (Integra Federal Circuit Brief); Brief for Defendant-Appellant Merck KGaA at 13-15, *Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003) (No. 02-1052, -1065) (Merck Federal Circuit Brief).[18] There is no question that these experiments comprised legitimate scientific research to assess the efficacy, mechanisms of action, and systemic effects of the peptides. *See* Integra Federal Circuit Brief at 6-7 (describing the experiments as "screening drug candidates," "toxicology, pharmacology, and pharmacokinetic research," and "screening commercially-valuable mimetics"). At trial and on appeal, Respondents acknowledged that these experiments comprised "'discovery-based research'" and a "search for the best drug candidate." *Id.* at 24; Merck Federal Circuit Brief at 16.

This Court should hold that both Section 271(e) and the experimental use exception to Section 271(a) apply to the pre-clinical experiments at issue. In regard to Section

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[17] This brief assumes for analysis that valid claims of Respondents' patents apply to the cyclic RGD peptides at issue.

[18] The experimental use exception was found to apply to earlier scientific analyses that are not now at issue. *See Integra LifeSciences I, Ltd. v. Merck KGaA*, No. CV.96 CV 1307-B(AJB), 2004 WL 2284001, at *2, *4-*5 (S.D.Cal. Sept. 7, 2004); Reply Brief for Defendant-Appellant Merck KGaA at 13, *Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003) (No. 02-1052, -1065) (distinguishing early "compound screening" from "further testing and analysis").

271(e), these experiments were not wholly unrelated to developing information in a research and development process leading to regulatory approval by the FDA. Rather, they were closely tied to that process. *See* Brief for the United States as Amicus Curiae at 2, 9-13, *Merck KGaA v. Integra LifeSciences I, Ltd.* (S. Ct. No. 03-1237) (on Petition for Certiorari). Because these experiments were performed with the intent to develop a commercially viable pharmaceutical product, they would not have qualified for the experimental use exception under the improperly narrow interpretation in *Roche* that Congress rejected.

Under the proper interpretation of Section 271(a), the experimental use exception also should be found to apply. The discovery based research activities at issue here constituted legitimate scientific research to evaluate the cyclic RGD peptides. *See, e.g., Integra LifeSciences I, Ltd.*, 331 F.3d at 874-76 (Newman, J., dissenting). Because there is no evidence of any act of infringement in this case, this Court (like the District Court in *Roche*) should not hesitate to reach the experimental use exception, notwithstanding the fact that Petitioner only asserts Section 271(e). *See* Supreme Court Rule 24(a) (the Court may consider plain errors "evident from the record and otherwise within its jurisdiction").

B. The Court Should Repudiate The Federal Circuit's Improperly Narrow Interpretations Of The Experimental Use Exception.

To assure that scientific research and competitive evaluation to develop improvements would occur during patent term, Congress has required since the beginning of American patent law an enabling disclosure of the invention as the *quid pro quo* for granting patent rights. *See* Patent Act of 1~~790, ch.~~ 7, § 2, 1 Stat. 109, 110 (1790) (currently codified as amended at 35 U.S.C. § 112, para. 1). Similarly, Congress since 1793 has allowed blocking

patents for improvements to patented inventions during the patent term. *See supra* note 11. As Judge Newman forcefully warned, "[w]ere such research [as that here] subject to prohibition by the patentee the advancement of technology would stop." *Integra LifeSciences I, Ltd.*, 331 F.3d at 875 (Newman, J., dissenting). Yet the Federal Circuit majority in this case would have declared the death of the experimental use exception had it been argued by Petitioner's counsel. *See id.* at 863 n.2 (also conflating experimental use with the *de minimis* doctrine) (*citing Embrex, Inc. v. Serv. Eng. Corp.*, 216 F.3d 1343, 1352-53 (Fed. Cir. 2000) (Rader, J. concurring), and *Deuterium Corp. v. United States*, 19 Ct. Cl. 624, 631 (Ct. Cl. 1990)). *Cf. Embrex, Inc.*, 216 F.3d at 1349 (upholding a jury finding of infringement for tests using a patented method of injecting birds to demonstrate the use of unpatented machines that were unsuccessfully offered for sale).

The failure of Petitioner to raise the experimental use exception in regard to the experiments at issue here is not surprising, given that Section 271(e) should apply. But it is deeply troubling. The dicta in *Roche* and the holding in *Embrex* substantially chill experimental use arguments and analyses of patent counsel. Petitioner's strategic choice, moreover, was made even before the Federal Circuit dramatically further limited the scope of the experimental use exception in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002).

Madey addressed legitimate research relating to a government contract performed by respected scientists within an academic research institution. *See id.* at 1353-54. The Federal Circuit, however, remanded the District Court's finding of experimental use, holding that "research projects with arguably no commercial application whatsoever . . . unmistakably further [academic research universities'] legitimate business objectives" and that experiments must have "no commercial application whatsoever" for

the experimental use exception to apply. *Id.* at 1362. Until *Madey*, and even after *Roche*, the patent bar understood that the experimental use exception applied to purely academic research performed without a use for profit. *See, e.g.*, Hantman, 67 J. Pat. Off. Soc'y at 633 ("[f]ew would deny the experimental use exception for research on patented technology performed at a university in furtherance of its educational function"). To the benefit of scientific research, technological development, and social welfare, academic researchers routinely ignored the possibility that their experiments might be held to infringe patent rights (even when they possessed future commercial intentions regarding their research results). *See* John P. Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, Patents in the Knowledge-Based Economy at 322-31 (Nat'l Research Council 2002).

These decisions are clearly changing perceptions in the patent bar regarding the experimental use exception. *See, e.g.*, Matt Fleischer-Black, *Benchmarks: Wake Up Call*, 3 IP L. & Bus. 26 (Oct. 2003) (*Madey* "came as a surprise to many university researchers and their lawyers" and "university officials have been warning that corporate lawyers, emboldened by the decision, could halt campus research and technological progress"); Cristina Weschler, *The Informal Experimental Use Exception: University Research After* Madey v. Duke University, 79 N.Y.U. L. Rev. 1536, 1536 n.1 (2004) ("It is widely recognized that use liability exists even when a researcher does not incorporate the patented material into a product that is ultimately sold."). It is critical that the practices of research scientists do not similarly change. *Cf.* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & Contemp. Probs. 289, 296 (2003) (because "patent law offers no significant experimental use exemption . . . it may be foolhardy for nonprofit researchers to rely on the forbearance of patent

holders"). The Patent Act's exclusive rights were premised on the ability of scientists to perform their research free from the threat of patent litigation and the tax of patent licensing negotiations and fees. The tax of licensing should apply only afterwards, and then only to commercial making, using, offering for sale, selling, or importing of infringing inventions (including blocking improvements).

Scientific discovery, competitive improvement, and public health are being adversely affected by the Federal Circuit's narrow interpretations of the experimental use exception. *See, e.g.*, Mildred K. Cho, et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. Molecular Diag. 3, 7 (Feb. 2003) (25% of surveyed clinical laboratory directors had stopped performing genetic tests because of patents or licenses, 53% had decided not to develop new tests, 69% paid royalties to use patented methods or reagents, and "virtually no respondents, including those from commercial laboratories, thought that the effects of patents and licenses on the cost, access, and development of genetic tests have been positive"); Jon F. Merz, et al., *Diagnostic Testing Fails the Test*, 415 Nature 577, 577-79 (2002) (30% of surveyed clinical medical labs ceased using or failed to develop genetic tests for haemochromatosis once a patent issued); Isaac Rabino, *How human geneticists in the US view commercialization of the Human Genome Project*, 29 Nature Gen. 15, 15-16 (Sept. 2001) (49% of surveyed American Society of Human Genetics' scientists reported that DNA patents had limited at least some of their research, and 75% disapproved of DNA patents). As the current legal perceptions regarding the experimental use exception take further hold, predictions of the adverse effects of the *Madey* decision may increasingly come true. *See, e.g.*, Walsh, et al., at 335 (noting that public understanding of *Madey* "could well chill some of the 'offending' biomedical research that is conducted in university settings").

The narrow interpretations of the experimental use exception by the Federal Circuit also place the United States in conflict with the international community, and are likely to result in scientific research, patent rights, and wealth leaving the United States. *See, e.g.*, John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 Berkeley Tech. L.J. 685, 718-19 (2002) (discussing patent law incentives to "outsource" scientific research). Many countries have adopted experimental use exceptions that apply more broadly than the Federal Circuit's interpretation and which are fully consistent with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement). *See* Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R, at ¶ 7.69 (Mar. 17, 2000) (the most common Article 30 exception, "scientific experimentation, during the term of the patent and without consent, is not an infringement"). For example, the Japanese Patent Law contains a broad and categorical codified experimental use exception.[19] In the developing world, many countries routinely except from infringement scientific and/or technological research (even when performed with a commercial motivation), and some expressly except competitive evaluation.[20]

[19] *See* Japan Patent Law, Art. 69(1) (1999), available at http://www.jpo.go.jp/shoukaie/patent.htm#69 ("The effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research."). Under this research exception, which is not limited to the product approval context, testing of a patented product for approval (rather than for technological improvement) is not an infringement. *See Request to Enjoin Sale of Medical Supplies* (S. Ct. Japan, Apr. 16, 1999), available at http://courtdomino2.courts.go.jp/schanrei.nsf/VM2/AB240DD41982AA3C49256D2700058227?OPENDOCUMENT (in Japanese).

[20] *See* Carlos M. Correa, *The International Dimension of the Research Exception*, at 19-25 (2004), at http://sippi.aaas.org/Correa%20-20International%20Exception.doc.

Further, because the exclusive right to sell has always prevented commercial competition in the United States in the market for selling patented products *to* researchers, the Federal Circuit and Respondents in this case overstate (as other *amici* likely will) concerns that a broad experimental use exception applicable to research tools would cause serious harm to the biotechnology industry or would threaten its ability to raise venture capital. *See Integra LifeSciences I, Ltd.*, 331 F.3d at 871-72; Integra Federal Circuit Brief at 17-18. The biotechnology industry is unlikely to lose significant revenue under a broad experimental use exception.[21] In any event, Congress implicitly rejected such concerns when enacting Section 271(e). The plain language of Section 271(e) applies fully to the making, using, offering for sale, selling, and importing of patented research tools "solely for uses reasonably relating" to research and development leading to approval of

[21] Most scientists are not engaged in manufacturing and will readily purchase rather than make patented products – such as microscopes, reagents, or biological materials – when they meet specifications and are commercially available for a reasonable fee. Scientists also sometimes enter into express licenses to use patented products or methods, even though they are not legally required to do so. *Cf.* Hantman, 67 J. Pat. Off. Soc'y at 643 (noting inconsistent licensing of the famous Cohen-Boyer patent and encouraging – twenty years ago – a test case that would demonstrate whether the experimental use exception applied to such research tools); Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 N.W.U. L. Rev. 1495, 1507 n.55 (2001) (estimating the average legal costs alone of negotiating a single patent license to be $50,000.00). But when such products or licenses are not available, are not offered on reasonable terms, or are subjected to unreasonable conditions, scientists are and should be free to make and use patented inventions without infringing any right of the patentee. Addressing similar concerns, Congress created a limited exception that assures that most patents for medical and surgical processes are unenforceable. *See* 35 U.S.C. § 287(c). The exception was needed because medical practice – unlike medical research – is not subject to the experimental use exception.

regulated products. Nothing in the legislative history suggests otherwise.

It is critically important that the Court take this opportunity to correct the Federal Circuit's improperly narrow interpretations of the experimental use exception in *Roche*, *Embrex*, *Madey*, and this case. This is likely to be the best (and, given the chill these cases exert, may be the only foreseeable) opportunity to set the historic and statutory record straight and to explain how Section 271(e) and Section 271(a) and its experimental use exception relate to each other. This Court should effectuate the legislative policy present since the inception of the Patent Act that the Federal Circuit's interpretations of the experimental use exception continue to subvert. By repudiating the Federal Circuit's narrow interpretations and by confirming that Congress intended a broad experimental use exception, the Court will better assure that patents do not chill scientific research and competitive evaluation through the threat of litigation and the tax of licensing. The Court will thereby effectuate the legislative balance designed to "Promote the Progress of Science and useful Arts." U.S. Const. Art. I, § 8, cl. 8.

CONCLUSION

For the foregoing reasons, the Court should hold that both Section 271(e) and the experimental use exception apply to the legitimate scientific experiments at issue here.

Respectfully submitted,

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